Citation:

Nakamura Y, Okamura T, Tamaki S, Kadowaki T, Hayakawa T, Kita Y, Okayama A, Ueshima H; NIPPON DATA80 Research Group. Egg consumption, serum cholesterol, and cause-specific and all-cause mortality: the National Integrated Project for Prospective Observation of Non-communicable Disease and Its Trends in the Aged, 1980 (NIPPON DATA80). *Am J Clin Nutr.* 2004;80(1):58-63.

PubMed ID: 15213028

Study Design:

Prospective cohort study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

- To examine the relations of egg consumption to serum cholesterol and cause-specific and all-cause mortality by using the NIPPON DATA80 (National Integrated Project for Prospective Observation of Non-communicable Disease And its Trends in the Aged, 1980) database

Inclusion Criteria:

- Participated in a medical history, physical examinations, blood tests, and a self-administered questionnaire on lifestyle, which included an essential nutritional survey

Exclusion Criteria:

- Past history of coronary artery disease or stroke
- Missing information on the baseline survey
- Lost to follow-up

Description of Study Protocol:

Recruitment

- Subjects were participants in the 1980 National Survey on Circulatory Disorders from 300 randomly selected health districts throughout Japan.

Design

- 14-year follow-up prospective cohort study from 1980 to 1994

Blinding used (if applicable)

not described

Intervention (if applicable)

not applicable

Statistical Analysis

- A one-way analysis of variance was used to compare means between the 5 groups stratified by egg consumption.
- A Cox proportional hazard model was used to calculate the age-adjusted and multivariate-adjusted relative risks for all-cause or cause-specific mortality.
- In multivariate analyses, potential confounders were entered as covariates.
- To rule out the possibility that subjects with a severe but subclinical disease might have affected the outcome, the above Cox analyses after excluding subjects who died within the initial 5 years of follow-up was performed.
- Tests of linear trends across groups with decreasing egg consumption were conducted by treating the median or representative values of egg consumption in the 5 categories as continuous variables.
- All P values were two-tailed, and $P<0.05$ was considered significant.

Data Collection Summary:

Timing of Measurements

- The baseline surveys were conducted by public health centers.
- Baseline blood pressures were measured by trained observers using a standard method. Hypertension was defined as systolic blood pressure≥140 mm Hg, diastolic blood pressure≥90 mm Hg, use of antihypertensive agents, or any combination of these.
- Height and weight were measured. BMI was calculated as weight in kg divided by the square of height in m.
- A lifestyle survey was carried out by using a self-administered questionnaire which included questions about the average consumption of 31 food items.
- Egg consumption was queried on the basis of 5 categories:≥2/d, ≈1/d, ≈1/2 d, ≈1-2/wk, and seldom.
- Public health nurses rechecked information with the subjects regarding consumption of eggs and other foods, and present and past medical histories.
- Non-fasting blood samples were drawn for measurement of serum cholesterol.
- The cause of death was confirmed by computer matching of data from the National Vital Statistics.

Dependent Variables

- Total cholesterol
- Death due to all-cause, stroke, ischemic heart disease (IHD), and cancer

Independent Variables

- Egg consumption

Control Variables

- Age, serum creatinine, total cholesterol, blood glucose, BMI, systolic and diastolic blood pressures, use of blood pressure lowering drugs, cigarette smoking, and alcohol intake

Description of Actual Data Sample:

Initial N: 13,771 were recruited at study initiation and 10,546 participated before exclusion.

Attrition (final N): 9,263 (5186 women and 4077 men) for the analyses indicating 12% dropout rate

Age: Participants were aged≥30 years at baseline in 1980

Ethnicity: Japanese

Other relevant demographics:

There was no significant difference in sex-specific mean total cholesterol concentration between the subjects who were lost to follow-up and those who were censored. Thus, the potential bias regarding the 870 subjects lost to follow-up was negligible.

Anthropometrics:

Whether groups were significantly different on BMI were not described.

Location: 300 health districts throughout Japan

Summary of Results:

Key Findings

• The subjects were categorized into 5 egg consumption groups on the basis of their responses to a questionnaire (≥2/d, 1/d, 1/2 d, 1-2/wk, and seldom). There were 69, 1396, 1667, 1742, and 315 women in each of the 5 groups, respectively.

• Age-adjusted total cholesterol (5.21, 5.04, 4.95, 4.91, and 4.92 mmol/L in the 5 egg consumption categories, respectively) was related to egg consumption (P<0.0001, analysis of covariance).

• In women, unadjusted IHD mortality and all-cause mortality differed significantly between the groups [IHD mortality: 1.1, 0.5, 0.4, 0.5, and 2.0 per 1000 person-years, respectively (P=0.008, chi-square test); all-cause mortality: 14.8, 8.0, 7.5, 7.5, and 14.5 per 1000 person-years,

respectively (P<0.0001, chi-square test)].

• In men, egg consumption was not related to age-adjusted total cholesterol.

• Cox analysis found that, in women, all-cause mortality in the 1-2-eggs/wk group was significantly lower than that in the 1-egg/d group, whereas no such relations were noted in men.

Author Conclusion:

• Limiting egg consumption may have some health benefits, at least in women in geographic areas where egg consumption makes a relatively large contribution to total dietary cholesterol intake.

Reviewer Comments:

The observed associations might be less valid due to several reasons. First, total energy intake was not collected to exclude those individuals who consumed extremely high and low calories. Second, food intake data was collected only once, which did not consider that dietary changes might occur overtime. Next, the validity and reliability of measures of egg consumption and 31-item food frequency questionnaire has not been validated for this cohort or described in this study. Finally, blinding was not used in this study.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes

1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	No
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A

5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	No
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	No
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	No
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes

	7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	N/A
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes